Complete Summary

GUIDELINE TITLE

The use of systemic fluoroquinolones.

BIBLIOGRAPHIC SOURCE(S)

Committee on Infectious Diseases. The use of systemic fluoroquinolones. Pediatrics 2006 Sep;118(3):1287-92. [26 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

All clinical reports and policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse (NGC): This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- July 08, 2008, Fluoroquinolones (ciprofloxacin, norfloxacin, ofloxacin, levofloxacin, moxifloxacin, gemifloxacin): A BOXED WARNING and Medication Guide are to be added to the prescribing information to strengthen existing warnings about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones for systemic use.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Bacterial infections, including:

- Exposure to aerosolized Bacillus anthracis
- Urinary tract infections caused by *Pseudomonas aeruginosa* or other multidrug-resistant, Gram-negative bacteria
- Chronic suppurative otitis media or malignant otitis externa caused by *P. aeruginosa*
- Chronic or acute osteomyelitis or osteochondritis caused by *P. aeruginosa*
- Exacerbation of pulmonary disease in patients with cystic fibrosis (CF) who have colonization with *P. aeruginosa*
- Mycobacterial infections
- Gram-negative bacterial infections in immunocompromised hosts
- Gastrointestinal tract infection caused by multidrug-resistant *Shigella* species, *Salmonella* species, *Vibrio cholerae*, or *Campylobacter jejuni*
- Bacterial septicemia or meningitis

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Otolaryngology
Pediatrics
Pulmonary Medicine
Urology

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide specific guidelines for the systemic use of fluoroquinolones in children

TARGET POPULATION

Patients younger than 18 years of age

INTERVENTIONS AND PRACTICES CONSIDERED

Systemic fluoroquinolones

MAJOR OUTCOMES CONSIDERED

- Effectiveness of therapy
- Drug related adverse events
- Fluoroquinolone resistance

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of Evidence

I: Evidence obtained from at least 1 properly randomized controlled trial

II-1: Evidence obtained from well-designed controlled trials without randomization

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than1 center or research group

II-3: Evidence obtained from multiple time series with or without the intervention; dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence

III: Opinions of respected authorities that are based on clinical experience, descriptive studies, and case reports or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The levels of evidence (I-III) are defined at the end of the "Major Recommendations" field.

Recommendations

The inappropriate use of fluoroquinolones in children and adults is likely to be associated with increasing bacterial resistance to these agents.

The use of fluoroquinolone in a child or adolescent may be justified in special circumstances after careful assessment of the risks and benefits for the individual patient. Although there is no compelling evidence supporting the occurrence of

sustained injury to developing joints in humans by a fluoroquinolone, the possibility that it occurs infrequently has not been excluded.

Circumstances in which fluoroquinolones may be useful include those in which (1) infection is caused by multidrug-resistant pathogens for which there is no safe and effective alternative and (2) parenteral therapy is not feasible and no other effective oral agent is available. Appropriate uses should be limited to the following:

- Exposure to aerosolized *Bacillus anthracis* to decrease the incidence or progression of disease (FDA licensed) (**evidence grade III**)
- Urinary tract infections caused by *Pseudomonas aeruginosa* (*P. aeruginosa*) or other multidrug-resistant, Gram-negative bacteria (FDA licensed for complicated *Escherichia coli* urinary tract infections and pyelonephritis attributable to *Escherichia coli* in patients 1 to 17 years of age) **(evidence grade II-2)**
- Chronic suppurative otitis media or malignant otitis externa caused by *P. aeruginosa* **(evidence grade II-3)**
- Chronic or acute osteomyelitis or osteochondritis caused by *P. aeruginosa* (not for prophylaxis of nail puncture wounds to the foot) **(evidence grade III)**
- Exacerbation of pulmonary disease in patients with cystic fibrosis (CF) who have colonization with *P. aeruginosa* and can be treated in an ambulatory setting **(evidence grade II-2)**
- Mycobacterial infections caused by isolates known to be susceptible to fluoroquinolones **(evidence grade III)**
- Gram-negative bacterial infections in immunocompromised hosts in which oral therapy is desired or resistance to alternative agents is present **(evidence grade II-1)**
- Gastrointestinal tract infection caused by multidrug-resistant *Shigella* species, *Salmonella* species, *Vibrio cholerae* or *Campylobacter jejuni* **(evidence grade II-2)**
- Documented bacterial septicemia or meningitis attributable to organisms with in vitro resistance to approved agents or in immunocompromised infants and children in whom parenteral therapy with other appropriate antimicrobial agents has failed **(evidence grade III)**
- Serious infections attributable to fluoroquinolones-susceptible pathogens(s) in children with life-threatening allergy to alternative agents **(evidence grade III)**

Definitions:

Quality of Evidence

I: Evidence obtained from at least 1 properly randomized controlled trial

II-1: Evidence obtained from well-designed controlled trials without randomization

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than1 center or research group

II-3: Evidence obtained from multiple time series with or without the intervention; dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence

III: Opinions of respected authorities that are based on clinical experience, descriptive studies, and case reports or reports of expert committees

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of fluoroquinolone use in children and adolescents

POTENTIAL HARMS

- The inappropriate use of fluoroquinolones in children and adults is likely to be associated with increasing bacterial resistance to these agents.
- Fluoroquinolones cause arthrotoxicity in juvenile animals and have been associated with reversible musculoskeletal events in both children and adults. Other adverse events associated with fluoroquinolones include central nervous system disorders, photosensitivity, disorders of glucose homeostasis, prolongation of QT interval with rare cases of torsade de pointes (often lethal ventricular arrhythmia in patients with long QT syndrome), hepatic dysfunction, and rashes.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Committee on Infectious Diseases. The use of systemic fluoroquinolones. Pediatrics 2006 Sep;118(3):1287-92. [26 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Sep

GUIDELINE DEVELOPER(S)

American Academy of Pediatrics - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Pediatrics

GUIDELINE COMMITTEE

Committee on Infectious Diseases

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee on Infectious Diseases, 2004-2005: Keith R. Powell, MD, *Chairperson*; Robert S. Baltimore, MD; Henry Bernstein, DO; Joseph A. Bocchini, Jr, MD; John S. Bradley, MD; Michael Brady, MD; Penelope H. Dennehy, MD; Robert W. Frenck, Jr, MD; David Kimberlin, MD; Sarah S. Long, MD; Julia A. McMillan, MD; Lorry G. Rubin, MD

Past Committee Members: Carol J. Baker, MD; Caroline B. Hall, MD; H. Cody Meissner, MD; Margaret B. Rennels, MD

Liaisons: Richard D. Clover, MD, American Academy of Family Physicians; Steven Cochi, MD, Centers for Disease Control and Prevention; Joanne Embree, MD, Canadian Paediatric Society; Marc A. Fischer, MD, Centers for Disease Control and

Prevention; Benjamin Schwartz, MD, National Vaccine Program Office; Mamodikoe Makhene, MD, National Institutes of Health; Douglas Pratt, MD, Food and Drug Administration; Jeffrey R. Starke, MD, American Thoracic Society; Jack Swanson, MD, Practice Action Group

Ex Officio: Larry K. Pickering, MD, Red Book Editor

Consultant: Edgar O. Ledbetter, MD

Staff: Alison Siwek, MPH

Committee on Infectious Diseases, 2003-2004: Margaret B. Rennels, MD, *Chairperson*; H. Cody Meissner, MD, Vice *Chairperson*; Carol J. Baker, MD; Robert S. Baltimore, MD; Joseph A. Bocchini, Jr, MD; John S. Bradley, MD; Penelope H. Dennehy, MD; Robert W. Frenck, Jr, MD; Caroline B. Hall, MD; Sarah S. Long, MD; Julia A. McMillan, MD; *Keith R. Powell, MD; Lorry G. Rubin, MD; Thomas N. Saari, MD

Liaisons: Richard D. Clover, MD, American Academy of Family Physicians; Steven Cochi, MD, Centers for Disease Control and Prevention; Joanne Embree, MD, Canadian Paediatric Society; Marc Fischer, MD, Centers for Disease Control and Prevention; Bruce Gellin, MD, MPH, National Vaccine Program Office; Mamodikoe Makhene, MD, National Institutes of Health; Douglas Pratt, MD, Food and Drug Administration; Jeffrey R. Starke, MD, American Thoracic Society

Ex Officio: Larry K. Pickering, MD, Red Book Editor

Staff: Martha Cook, MS

* Lead author

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

All clinical reports and policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Pediatrics (AAP) Policy Web site.

Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on December 7, 2006. The information was verified by the guideline developer on December 22, 2006. This summary was updated by ECRI Institute on July 28, 2008 following the U.S. Food and Drug Administration advisory on fluoroquinolone antimicrobial drugs.

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

Date Modified: 9/15/2008